

EPA Jacket 69361-48

PROCESSING REQUEST

Reg # 69361-48

Decision # 497484

Description: New Product Registration

Electronic Label & Letter
(see PPLS):

OR

**Non Electronic
Label & Letter**
(Scanning required):

☒ Dated: 4/2/15

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 11/17/2014

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Maryam K. Muhammad

Division: RD

Phone: 703-347-0301

Date: 04/02/2015



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

69361-48

Date of Issuance:

04/02/2015

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

REPAR STREPTOMYCIN 50

Name and Address of Registrant (include ZIP Code):

N. Bhushan Mandava
Agent for Repar Corporation
c/o Mandava Associates, LLC
1050 Connecticut Avenue, N. W., Suite 1000
Washington, DC 20036

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Hope Johnson, Product Manager 21
Fungicide Branch, Registration Division (7505P)

Date:

04/02/2015

EPA Form 8570-6

Registration Notice Conditional v. 20141114

2. You are required to comply with the data requirements described in the DCI Order identified below:

- a. Streptomycin Sulfate GDCI-006310-27845
GDCI-006310-897

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 69361-48."
 - Add appropriate Net Contents information and an EPA Establishment Number
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/17/2014

If you have any questions, you may contact Maryam K. Muhammad at 703-347-0301 or via email at Muhammad.maryam@epa.gov.

Enclosure: Product Chemistry Review of New End Use Product
Accepted Label

REPAR STREPTOMYCIN 50

Agricultural Streptomycin

For control of halo blight of beans seed treatment (only in commercial seed treatment plants) and control of fire blight in apples and pears

ACTIVE INGREDIENT:	By Wt.
Streptomycin Sulfate*.....	62.65%
INERT INGREDIENTS.....	37.35%
TOTAL.....	100.00%

*Equivalent to 50% streptomycin base

KEEP OUT OF REACH OF CHILDREN

CAUTION/PRECAUCIÓN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you **DO NOT** understand the label, find someone to explain it to you in detail.)

For Chemical Spill, Leak, Fire or Exposure Call CHEMTREC (800) 424-9300
For medical emergency Assistance, call the National Capital Poison Control Center
1-800-222-1222.

SEE SIDE PANEL FOR ADDITIONAL FIRST AID AND PRECAUTIONARY
STATEMENTS

NET CONTENTS: _____ Lbs.

MANUFACTURED FOR
REPAR CORPORATION
P.O. BOX 4321
SILVER SPRING, MD 20914

EPA Reg. No.: 69361-UI
EPA Est. No.:

ACCEPTED

04/02/2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 69361-48

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS & DOMESTIC ANIMALS
CAUTION/PRECAUCIÓN

Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or physician for treatment advice.
If on skin or: clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or physician for treatment advice.
If Inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth- to mouth, if possible.• Call a poison control center or physician for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergency Assistance, call the National Capital Poison Control Center 1-800-222-1222.	

For chemical emergency: spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear
- A particulate respirator with an N, R, or P filter, NIOSH approval prefix TC-84-A.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product may be hazardous to aquatic plants. Do not apply directly to water, areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water. When disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product through any type of irrigation system. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instruction and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants soil or water, wear:

- Coveralls
- Chemical-resistant gloves made of a waterproof material
- Shoes plus socks
- Protective eyewear

CROP USE DIRECTIONS

Control of Fire Blight of Apples and Pears – Directions for Use

Crop	Rate	First Spray	Use Directions/Restrictions
Pears (West Coast Area)	9.6oz. Repar Streptomycin 50 per acre (equivalent to 60 ppm at 600 gals. per acre).	10% bloom	Repeat at 5-day intervals until all late bloom is over. Continue to spray at 5 to 7-day intervals to control shoot and fruit infections. Restrictions: Do not make more than 15 additional applications. Do not apply within 30 days of harvest.
Pears (Other Areas)	8-16oz. Repar Streptomycin 50 per acre (equivalent to 50-100 ppm at 600 gals. per acre).	Spray trees at 20-30% bloom.	Spray trees every 3-4 days during blossom time. Apply sprays after petal fall every 10-14 days to control twig blight. Restrictions: Do not make more than 8 additional applications after blossom spray applications. Do not apply within 30 days of harvest.
Apples (West Coast Area)	9.6oz. Repar Streptomycin 50 per acre (equivalent to 60 ppm at 600 gals. per acre).	Full Bloom	Apply at petal fall and late secondary bloom. Continue to spray at 5 to 7-day intervals to maintain disease control. Restriction: Do not apply within 50 days of harvest.
Apples (Other Areas)	8-16oz. Repar Streptomycin 50 per acre (equivalent to 50-100 ppm at 600 gals. per acre).	Spray trees at 20-30% bloom.	Spray trees every 3-4 days during blossom time. Apply sprays after petal fall every 10-14 days to control twig blight. Restrictions: Do not make more than 8 additional applications after blossom spray applications. Do not apply within 50 days of harvest.

MIXING INSTRUCTIONS FOR APPLE AND PEAR

Concentration Desired	Quantity of Streptomycin 50 in Ounces Per Volume of Water			
	50 gals	100 gals	500 gals	600 gals
50 ppm	2/3	1 1/3	6 2/3	8 (1/2 lb.)
60ppm	0.8	1.6	8 (1/2 lb.)	9.6
100ppm	1 1/3	2 2/3	13 1/3	16 (1 lb.)

Information regarding use of **Repar Streptomycin 50** may be obtained from your local Agricultural Extension Agent or State Experimental Station.

Seed Treatment – Control of Halo Blight of Beans

Seed Bag Label Requirements

The Federal Seed Act requires that containers containing treated seeds shall be labeled with the following statements:

- This seed has been treated with **Repar Streptomycin 50**, a fungicide containing streptomycin sulfate.
- Do not use treated seed for feed, food, or oil purposes.

The U.S. Environmental Protection Agency requires the following statements on containers containing seed treated with streptomycin sulfate:

- Store treated seed away from food and feedstuffs.
- Do not allow children, pets or livestock to have access to treated seeds.
- Wear long pants, long-sleeved shirt, shoes and socks, chemical resistant gloves, and a NIOSH approved respirator with approval prefix TC-84-A when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- Dispose of seed packaging or containers in accordance with local requirements.
- Excess treated seed may be used for ethanol production if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.

Crop/Disease	Concentration	Use Directions
Beans – Seed Protection (For Control of Surface Infection)	0.18-0.91 oz./cwt of seed	Use higher specified rate of product when halo blight pressure is severe. This product dissolves in water and is compatible with fungicides and insecticides. Slurry rates will vary with components and treatment equipment. Apply this product using commercial mist, spray, or other application equipment.

RESTRICTIONS: For use by commercial treaters only. Not for on farm use or at planting time. Do not use treated seeds for food or feed purposes.

MIXING INSTRUCTIONS FOR SEED TREATMENT

Concentration Desired	Quantity of Streptomycin 50 Per Volume of Water			
	1 pt.	1 qt.	1 gal.	5 gals.
1%	0.3 oz. (9.5 g)	0.6 oz. (19.0 g)	2 2/3 oz.	13 1/3 oz.
2%	0.6 oz. (19.0 g)	1 1/3 oz. (38.0 g)	5 1/3 oz.	26 2/3 oz.
5%	1.5 oz. (47.5 g)	3.0 oz. (90.0 g)	13 1/3 oz.	66 2/3 oz.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep tightly closed. Store at cool temperature when possible, and with minimal exposure to atmosphere.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

[Nonrefillable plastic containers] CONTAINER:

[Nonrefillable Containers 5 Gallons or Less:]

Triple rinse as follows: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration. Do not burn unless permitted by state and local ordinance. If burned stay out of smoke.

[Nonrefillable containers larger than 5 Gallons:]

Triple rinse as follows: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration. Do not burn unless permitted by state and local ordinance. If burned stay out of smoke.

[Nonrefillable bags]

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless permitted by state and local ordinance. If burned, stay out of smoke.

[Refillable drum with a Nonrefillable liner]

Refill this container with pesticide only. Do not use this container for any other purpose. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment or a mix tank. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of REPAR CORPORATION or Seller. To the extent consistent with applicable law, All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold REPAR CORPORATION and Seller harmless for any claims relating to such factors.

REPAR CORPORATION warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or REPAR CORPORATION and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, REPAR CORPORATION MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall REPAR CORPORATION or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF REPAR CORPORATION AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF REPAR CORPORATION OR SELLER, THE REPLACEMENT OF THE PRODUCT.

REPAR CORPORATION and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of REPAR CORPORATION.

Muhammad, Maryam K.

From: Srinivas Mandava, M.D. <Srini@Mandava.com>
Sent: Monday, March 23, 2015 3:35 PM
To: Muhammad, Maryam K.
Cc: Johnson, Hope; mandava@compuserve.com
Subject: RE: EPA REG. NO. 69361-UI Formulators Exemption and Data Matrix Deficiencies
Attachments: Streptomycin 50 Form 8570-34 (03-23-15).pdf; Streptomycin 50 Form 8570-35 Agency Internal Use Copy (03-23-15).pdf; Streptomycin 50 Form 8570-35 Public File Copy (03-23-15).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Maryam:

Thank you for your email from Thursday March 19, 2015. Please find enclosed the updated Data Matrix (EPA Form 8570-35) and the Certification with Respect to Citation of Data (EPA Form 8570-34) which includes the generic data section for the Pesticide Data Submitters for Streptomycin Sulfate for Repar Streptomycin 50 (EPA Reg. No. 69361-UI).

By means of this email we are formally acknowledging the withdrawal of the Formulators Exemption Statement (EPA Form 8570-27).

Thank you for your assistance in this matter. We hope to receive the EPA registration for this product soon.

Best Regards,

Srini

Srinivas Mandava, M.D.
Mandava Associates, LLC
1050 Connecticut Avenue, N.W.
Suite 1000
Washington, D.C. 20036
Tel: (202) 223 - 1424
Fax: (202) 223 - 0141

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**

From: Muhammad, Maryam K. [mailto:Muhammad.Maryam@epa.gov]
Sent: Thursday, March 19, 2015 9:35 AM

To: Bhushan Mandava

Subject: EPA REG. NO. 69361-UI Formulators Exemption and Data Matrix Deficiencies

Hi Mr. Mandava,

Per our phone conversation on 3/19/2015, you have agreed to withdraw the formulators exemption form since none of the cited technicals are being used to formulate your product and you own the technical 69361-8 that you are using to formulate your product. In addition, you have agreed to revise the Data Matrix to include a generic data section that lists the Pesticide Data Submitters List for Streptomycin Sulfate.

Please make these changes and formally confirm this via email or on your company letter head.

A resubmitted data matrix must be sent to us before we can further process this registration.

Thank you for your cooperation.

I look forward to hearing from you soon.

Best Regards.

Maryam K. Muhammad

Biologist

Registration Division

EPA Office of Pesticide Programs

(703) 347-0301

Muhammad, Maryam K.

From: Muhammad, Maryam K.
Sent: Thursday, March 19, 2015 9:35 AM
To: 'Bhushan Mandava'
Subject: EPA REG. NO. 69361-UI Formulators Exemption and Data Matrix Deficiencies

Hi Mr. Mandava,

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Please make these changes and formally confirm this via email or on your company letter head.

A resubmitted data matrix must be sent to us before we can further process this registration.

Thank you for your cooperation.

I look forward to hearing from you soon.

Best Regards.

Maryam K. Muhammad
Biologist
Registration Division
EPA Office of Pesticide Programs
(703) 347-0301

Muhammad, Maryam K.

From: Muhammad, Maryam K.
Sent: Wednesday, February 25, 2015 10:36 AM
To: 'Bhushan Mandava'
Subject: RE: EPA REG. NO. 69361-UI Registration Status

Mr. Mandava.

We have received your updated label and response to the 75 day deficiency letter for EPA REG. NO. 69361-UI. Can you please email me an electronic highlighted and incorporated copy as well so that we can complete your registration.

Thank you

From: Bhushan Mandava [mailto:mandava@compuserve.com]
Sent: Wednesday, February 04, 2015 4:48 PM
To: Muhammad, Maryam K.
Subject: RE: EPA REG. NO. 69361-UI Registration Status

Thank you.

N. Bhushan Mandava
Mandava Associates, LLC
1050 Connecticut Avenue, N.W.
Suite 1000
Washington, D.C. 20036
Tel: (202) 223 - 1424
Fax: (202) 223 - 0141

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From: Muhammad, Maryam K. [mailto:Muhammad.Maryam@epa.gov]
Sent: Tuesday, February 03, 2015 2:00 PM
To: Bhushan Mandava
Subject: EPA REG. NO. 69361-UI Registration Status

Dear Mr. Mandava:

The Agency has reviewed your Application for Pesticide Registration EPA Reg. No **69361-UI**. We have found deficiencies regarding your application that need to be addressed in order to move forward with the registration of this new product. . Please see attached letter for details concerning your application.

We will also be mailing the letter and the review from our chemistry division (CITAB) to you as well.

Please respond to this message confirming that you have received this message.

If you have questions concerning this letter, please contact me at 703-347-0301 or via email at Muhammad.maryam@epa.gov.

Thank you for your time.

Regards,

Maryam K. Muhammad
Biologist
Registration Division
EPA Office of Pesticide Programs
(703) 347-0301

MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036
Telephone: (202)-223-1424/1747 • Fax: (202)-223-0141 • E-MAIL: Mandava@compuserve.com

February 23, 2015

HAND DELIVERED

Hope Johnson
Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

SUBJECT: Response to your February 3, 2015 Letter re. Registration Application
Repar Streptomycin 50
EPA File Symbol: 69361-UI
Application Date: 11-10-14
EPA Receipt date: 11-19-14
OPP Decision No.: D-497484

Company: Repar Corporation

Dear Ms. Johnson:

This letter is in response to your February 3, 2015 letter regarding the subject product registration (EPA File No.: 69361-UI). The Agency identified the following deficiencies as identified in your February 3, 2015 letter:

- 1) The nominal concentration on the CSF is not calculated correctly.
- 2) The ingredient statement on the label is not correct.

We have carefully reviewed the above deficiencies and the following is our response.

Deficiency #1: We have reviewed the CSF. We reported 62.65% as the nominal concentration in the CSF. We note that the product chemistry review (DP Barcode No.: D424836) is in agreement with the nominal concentration reported on our CSF. [Comments from Product Chemistry Reviewer: Basic CSF dated 11/17/15 will be accepted after the revised label is acceptable.]

Corrective Action: We have not taken any action based on the above comment from the product chemistry review.

Deficiency #2: As stated in the product chemistry review, the percent active ingredient did not correspond to nominal concentration reported on the CSF. (As per the regulations, the nominal concentration on the CSF must be the same as the percent active ingredient on the label ingredient statement.)

Corrective Action: The percent active ingredient on the label is corrected to 62.65%.

Ms. Hope Johnson (PM 21)
February 23, 2015

Page 2

Other items to your attention:

1) Re. Substantial Similarity

The product chemistry review shows that our product (EPA File Symbol: 69361-UI) is not substantially similar to cited product (EPA Reg. No.: 55146-98).

We would like to bring to your attention that it is our understanding that the label ingredient statement for AI must be the same for all streptomycin 50 products regardless of the purity of the source product (which is [REDACTED]). In the EPA database, we found the registrations for Streptomycin 50 for the following products:

<u>Product Name:</u>	<u>EPA Reg. No.</u>	<u>Nominal Concentration</u>	<u>Purity of the source product concentration</u>
AS-50 Agricultural Streptomycin	55146-98	65.80%	[REDACTED]
Agri-Seed 50 WP	80990-3	65.80%	[REDACTED]
Ag- Streptomycin	264-974	62.60%	-----
Repar Streptomycin 50	69361-UI	62.65%	[REDACTED]

We note that the nominal concentrations on the product labels are different for the above products (containing streptomycin 50), whereas in the case of the registrations for Streptomycin 17, all registrants reported 22.4% AI on their labels.

We do not know why there is a discrepancy on the AI percent on label ingredient statement in the case of Streptomycin 50. Repar and Bayer reported about 62.60% , whereas Nufarm and Geo Logic (aka Agrosource, Inc.) reported 65.8% as the AI content on their labels.

May we request you to review why there is a discrepancy in the percent of AI on the ingredient statements on the labels.

2) Re. Directions for Use –

Since all products for Streptomycin 50 are considered to be the same or substantially similar, in Repar’s opinion, the Directions for Use should be the same.

Ms. Hope Johnson (PM 21)
February 23, 2015

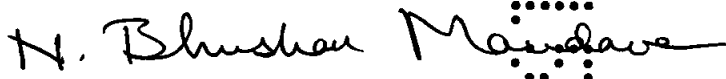
Page 3

Since we cited the product containing EPA Reg. No. : 55146-98 is substantially similar to our product (EPA File Symbol : 69361-UI), we used the same language for the label Directions for Use as shown in EPA Reg. No. : 55146-98. We do not think that there is any need to change the Directions for Use in our label.

We have enclosed the revised label for your review and approval.

If there are further questions, please contact us at 202-223-1424.

Sincerely,

A handwritten signature in black ink, reading "N. Bhushan Mandava". The signature is fluid and cursive, with the first name "N." and last name "Mandava" clearly distinguishable. To the right of the signature, there is a vertical column of dots, likely a scanning artifact or a placeholder for a stamp.

N. Bhushan Mandava, Ph.D.
Agent for Repar Corporation

Enclosure
Cc: Srinivas Mandava, M.D.

REPAR STREPTOMYCIN 50

Agricultural Streptomycin

For control of halo blight of beans seed treatment (only in commercial seed treatment plants) and control of fire blight in apples and pears

ACTIVE INGREDIENT:

Streptomycin Sulfate*.....

By Wt

62.65%

INERT INGREDIENTS.....

37.35%

TOTAL.....100.00%

*Equivalent to 50% streptomycin base

KEEP OUT OF REACH OF CHILDREN

CAUTION/PRECAUCIÓN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you **DO NOT** understand the label, find someone to explain it to you in detail.)

For Chemical Spill, Leak, Fire or Exposure Call CHEMTREC (800) 424-9300

**For medical emergency Assistance, call the National Capital Poison Control Center
1-800-222-1222.**

SEE SIDE PANEL FOR ADDITIONAL FIRST AID AND PRECAUTIONARY
STATEMENTS

NET CONTENTS: _____ Lbs.

MANUFACTURED FOR
REPAR CORPORATION
P.O. BOX 4321
SILVER SPRING, MD 20914

EPA Reg. No.: 69361-UI

EPA Est. No.:

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS & DOMESTIC ANIMALS
CAUTION/PRECAUCIÓN

Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

FIRST AID	
If in eyes:	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or physician for treatment advice.
If on skin or: clothing	•Take off contaminated clothing. •Rinse skin immediately with plenty of water for 15-20 minutes. •Call a poison control center or physician for treatment advice.
If Inhaled:	• Move person to fresh air. • If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth- to mouth, if possible. •Call a poison control center or physician for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergency Assistance, call the National Capital Poison Control Center 1-800-222-1222.	

For chemical emergency: spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear
- A particulate respirator with an N, R, or P filter, NIOSH approval prefix TC-84-A.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product may be hazardous to aquatic plants. Do not apply directly to water, areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water When disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product through any type of irrigation system. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instruction and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants soil or water, wear:

- Coveralls
- Chemical-resistant gloves made of a waterproof material
- Shoes plus socks
- Protective eyewear

CROP USE DIRECTIONS

Control of Fire Blight of Apples and Pears – Directions for Use

Crop	Concentration	First Spray	Follow Up Spray Schedule
Pears (West Coast Area)	9.6oz. Repar Streptomycin 50 per acre (equivalent to 60 ppm at 600 gals. per acre).	10% bloom	Repeat at 5-day intervals until all late bloom is over. Do not make more than 15 additional applications. Continue to spray at 5 to 7-day intervals to control shoot and fruit infections. Do not apply within 30 days of harvest.
Apples (West Coast Area)	9.6oz. Repar Streptomycin 50 per acre (equivalent to 60 ppm at 600 gals. per acre).	Full Bloom	Apply at petal fall and late secondary bloom. Continue to spray at 5 to 7-day intervals to maintain disease control but not later than 50 days before harvest.
Apples (Other Areas)	8-16oz. Repar Streptomycin 50 per acre (equivalent to 50-100 ppm at 600 gals. per acre).	Spray trees at 20-30% bloom.	Spray trees every 3-4 days during blossom time. Apply sprays after petal fall every 10-14 days to control twig blight. Do not make more than 8 additional after blossom spray applications. Do not apply within 30 days of harvest.
Pears (Other Areas)	8-16oz. Repar Streptomycin 50 per acre (equivalent to 50-100 ppm at 600 gals. per acre).	Spray trees at 20-30% bloom.	Spray trees every 3-4 days during blossom time. Apply sprays after petal fall every 10-14 days to control twig blight. Do not make more than additional after blossom spray applications. Do not apply within 30 days of harvest.

MIXING INSTRUCTIONS FOR APPLE AND PEAR

Concentration Desired	Quantity of Streptomycin 50 in Ounces Per Volume of Water			
	50 gals	100 gals	500 gals	600 gals
50 ppm	2/3	1 1/3	6 2/3	8 (1/2 lb.)
60ppm	0.8	1.6	8 (1/2 lb.)	9.6...
100ppm	1 1/3	2 2/3	13 1/3	16 (1 lb.)

Information regarding use of **Repar Streptomycin 50** may be obtained from your local Agricultural Extension Agent or State Experimental Station.

Seed Treatment – Control of Halo Blight of Beans

Seed Bag Label Requirements

The Federal Seed Act requires that containers containing treated seeds shall be labeled with the following statements:

- This seed has been treated with [insert product], a fungicide containing streptomycin sulfate.
- Do not use treated seed for feed, food, or oil purposes.

The U.S. Environmental Protection Agency requires the following statements on containers containing seed treated with streptomycin sulfate:

- Store treated seed away from food and feedstuffs.
- Do not allow children, pets or livestock to have access to treated seeds.
- Wear long pants, long-sleeved shirt and protective gloves when handling treated seed.
- Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting.
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- Dispose of seed packaging or containers in accordance with local requirements.
- Excess treated seed may be used for ethanol production if (1) by-products are not used for livestock feed and (2) no measurable residues of pesticide remain in ethanol by-products that are used in agronomic practice.

Crop/Disease	Concentration	Use Directions
Beans – Seed Protection (For Control of Surface Infection)	0.18-0.91 oz./cwt of seed	Use higher rate of product when halo blight pressure is severe. This product dissolves in water and is compatible with fungicides and insecticides. Slurry rates will vary with components and treatment equipment. Apply this product using commercial mist, spray, or other application equipment.

For use by commercial treaters only. Not for on farm use or at planting time. Do not use treated seeds for food or feed purposes.

MIXING INSTRUCTIONS FOR SEED TREATMENT

Concentration Desired	Quantity of Streptomycin 50 Per Volume of Water			
	1 pt.	1 qt.	1 gal.	5 gals.
1%	0.3 oz. (9.5 g)	0.6 oz. (19.0 g)	2 2/3 oz.	13 1/3 oz.
2%	0.6 oz. (19.0 g)	1 1/3 oz. (38.0 g)	5 1/3 oz.	26 2/3 oz.
5%	1.5 oz. (47.5 g)	3.0 oz. (90.0 g)	13 1/3 oz.	66 2/3 oz.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Keep tightly closed. Store at cool temperature when possible, and with minimal exposure to atmosphere.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

[Nonrefillable plastic containers] CONTAINER:

[Nonrefillable Containers 5 Gallons or Less:]

Triple rinse as follows: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers are also disposable by incineration. Do not burn unless permitted by state and local ordinance. If burned stay out of smoke.

[Nonrefillable containers larger than 5 Gallons:]

Triple rinse as follows: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Plastic containers are also disposable by incineration. Do not burn unless permitted by state and local ordinance. If burned stay out of smoke.

[Nonrefillable bags]

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn unless permitted by state and local ordinance. If burned, stay out of smoke.

[Refillable drum with a Nonrefillable liner]

Refill this container with pesticide only. Do not use this container for any other purpose. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment or a mix tank. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner required for its liner.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials, resistant strains or other influencing factors in the use of the product, which are beyond the control of REPAR CORPORATION or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold REPAR CORPORATION and Seller harmless for any claims relating to such factors.

REPAR CORPORATION warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or REPAR CORPORATION and Buyer and User assume the risk of any such use. REPAR CORPORATION MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall REPAR CORPORATION or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF REPAR CORPORATION AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF REPAR CORPORATION OR SELLER, THE REPLACEMENT OF THE PRODUCT.

REPAR CORPORATION and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of REPAR CORPORATION.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

February 3, 2015

OPP Decision Number: D-497484

N. Bhushan Mandava
Agent for Repar Corporation
c/o Mandava Associates, LLC
1050 Connecticut Avenue, N. W., Suite 1000
Washington, DC 20036

Subject: Label & Data Deficiency
Product Name: REPAR STREPTOMYCIN 50
EPA File Symbol: 69361-UI
Application Date: 11-19-14
EPA Receipt Date: 11-19-14

Dear Mr. Mandava:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in a telephone conversation on February 3rd, 2015, pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **April 19th, 2015** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your

application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

- 1) The nominal concentration on the CSF is not calculated correctly. See the attached Product Chemistry review for details.
- 2) The Ingredient Statement on the label is not correct. It must be revised to reflect the same revised nominal concentration the CSF must have.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on **April 10th, 2015**. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **March 27th, 2015** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later **March 27th, 2015** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **March 27th, 2015**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application.

Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **March 27th, 2015**, by contacting Maryam Muhammad by telephone on 703-347-0301 or by email at muhammad.maryam@epa.gov or Hope Johnson by phone on 703-305-5410 or by email at johnson.hope@epa.gov during the hours of 8 am to 5:30 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Hope Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Product Chemistry Review dated 1/14/2015; DP424836



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: D424836, File Symbol No. 69361-UI, PRODUCT NAME:
STREPTOMYCIN 50, PC Code(s):006310, Decision No., 497484, Action Code: R 300,
Food Use: Yes [X]

DATE OUT: 01/14/15

SUBJECT: Product Chemistry Review of New End Use Product
Product Name: STREPTOMYCIN 50

FROM: Indira Gairola, Product Chemistry Team
CITAB / Registration Division (7505P)

TO: Maryam Muhammad / Hope Johnson PM 21
Fungicide Branch/Registration Division (7505P)

Company Name: REPAR CORP.
Formulation Type: Fungicide: (off white solid powder)

INTRODUCTION:

The registrant submitted an application for registration of the new end use product "STREPTOMYCIN 50". Registrant has submitted Basic CSF dated 11/17/14. Applicant is submitting MRID #s 495151-01 for product chemistry data to support this registration application. Applicant claims the product to be substantially similar to EPA Reg. #55146-98. CITAB (Chemistry Team) has been asked to determine the acceptability of the aforementioned product chemistry data and CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient (s) 62.65%) Streptomycin.
2. Has the registrant claimed substantial similarity to a registered product?

[] NO [X] Yes [] NA; if yes give the registration number of the cited product.
EPA Reg. # 55146-98

3. All of the source materials of the active ingredient are derived from registered sources-
[X] Yes [] No [] [] Pending Registration

4. All inert ingredients have been screened by IIAB and found to be approved for the
proposed labeled food uses. [X] Yes

5. Confidential Statement of Formula(s):

[X] Proposed Basic dated 11/17/14 Resubmitted [] NA

[NA] Proposed Alternate:

Proposed Alternate comply with 40CFR§152.43: [] Yes; [] No [X] NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product
label (PR Notice 91-2)

[X] Yes; [] No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs. other
ingredient?)

[X] Yes; [] No; if not, explain below:

Metallic equivalent: [X] NA

Isomeric ratios [X] NA

Soluble Arsenic [X] NA

Acid Equivalent [X] NA

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: [] Yes [X] No [] NA

Methanol at > 4%: [] Yes [X] No [] NA

Sodium nitrate/Sodium nitrite: [] Yes [X] No [] NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR
§156.78

for: flammability, explosive potential or electric insulator breakdown?

[] Yes No [X]

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

[] Yes, [] No; [X] NA; if not, explain below:

d. Label requires an additional Storage and Disposal statement: [] Yes [X] No; if yes
Explain below:

Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the table below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	495151-01 CSF 11/17/14
830.1600	Description of materials used to produce the product		X		A	495151-01
830.1650	Description of formulation process		X		A	495151-01
830.1670	Discussion on the formation of impurities		X		A	495151-01
830.1700	Preliminary analysis			NA		
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	
		Proposed Limits			N	
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	495151-01

A = Acceptance, N = Not Acceptable, G = Data Gap,
W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Off white solid powder	A	495151-01
830.6315	Flammability	Does not contain any flammable or combustible liquids	A	495151-01
830.6314	Oxi/ Red	Does not contain any oxidizing or reducing agents reagents	A	495151-01
830.6316	Explodability	Does not contain any explosive substances	A	495151-01
830.6320	Corrosion Characteristic	Does not contain any corrosive agents	W	
830.6317	Storage Stability	Was conducted for 4 yrs @ 25 °C+2 °C at 0, 3, 6, 9,12,18,24, - 48 months	A	495151-01
830.7000	pH	5-6	A	495151-01
830.7100	Viscosity	Solid	NA	495151-01
830.7300	Density (units)	22 lbs /cubic ft.	A	495151-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable.

CONCLUSIONS:

CITAB (Chemistry Team) has reviewed Basic CSF dated 11/17/14 and product chemistry data corresponding to guideline 830 series, group A & group B for the proposed subject product "STREPTOMYCIN 50" and concluded:

1. The data corresponding to 830 series group A for the proposed subject product "STREPTOMYCIN 50 are not completely acceptable. Nominal concentration of the active ingredient 65.8% as stated on the label does not match the basic CSF dated 11/17/14 and is not correctly calculated. It calculates out to be 62.65% based on the figures stated on the CSF. Correction is required on the label claim to match the basic CSF. Data corresponding to 830 series group A are not fulfilled completely.
2. Product chemistry Data for 830 series group B are acceptable.
3. Basic CSF dated 11/17/14 will be accepted after the revised label is determined acceptable.
4. Applicant has stated that data for one-year storage stability (guideline 830.6317) was conducted for 4 years @ 25 °C+2 °C at 0, 3, 6, 9, 12, 18, 24, till 48 months and requested a waiver for corrosion characteristics (guideline 830.6320).
5. The subject product is not considered to be substantially similar to EPA Reg. # 55146-98 from product chemistry point of view, there is difference in % of active ingredient and inert ingredients as stated on the Basic CSF.
6. The proposed label was screened as it pertains to the product chemistry requirements.
7. The final review of the proposed label and uses are the purview of the PM team.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 1, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-497484
EPA File Symbol or Registration Number: 69361-UI
Product Name: STREPTOMYCIN 50
EPA Receipt Date: 19-Nov-2014
EPA Company Number: 69361
Company Name: REPAR CORP

N. BHUSHAN MADAVA
MANDAVA ASSOCIATES, LLC
REPAR CORP
1050 CONN. AVE., N.W., SUITE 1000
WASHINGTON, DC 20036

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval; and we will process a refund of your \$75 overpayment after this action has been completed. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Theresa Downs*
Front End Processing Staff
Information Technology & Resources Management Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

~~CONTAINS CBI DO NOT RELEASE TO REGISTRANT~~

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 69361-UI/REPAR Streptomycin 50
DP Barcode: 424175
PC Code: 006310

From: Marianne Lewis, Biologist
IVB3
Registration Division (7505P)

To: Hope Johnson, PM 21
Fungicide Branch
Registration Division (7505P)

Applicant: Repar Corporation
P.O. Box 4321
Silver Spring, MD 20914

Marianne Lewis
11/28/14
JCR

FORMULATION FROM EPA Reg. No. 69361-UI LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Streptomycin sulfate:	65.8%
<u>Inert Ingredient(s):</u>	34.2%
Total	100.0%

BACKGROUND: The registrant is claiming to be substantially similar to EPA Reg. No. 55146-98 and is doing a 'cite all' to support the registration of their product, EPA Reg. No. 69361-UI. After reviewing the CSF's from both products it has been determined that the subject product is substantially similar to EPA Reg. No. 55146-98 which was transferred multiple times. Five of the six required acute studies were conducted on a previous product number, EPA Reg. No. 618-100. However, the tox review indicated that an inhalation study was not done and it was still outstanding. After reviewing the database and the jackets I have not been able to determine whether or not this study was ever conducted. So it is still probably outstanding. Haven't been able to locate any acute inhalation studies done on the technical either. Don't know why this product was registered. The cited product has respirator language on it so therefore the subject product will also have to have it on their label. The subject product will be assigned the following Toxicity Categories: acute oral (81-1) – IV; acute dermal (81-2) – III; acute inhalation (81-3) – outstanding; primary eye irritation (81-4) – III; primary dermal irritation (81-5) – III. The subject product will be classified as a non sensitizer (81-6).

RECOMMENDATIONS:

- The subject product will be assigned the four (81-1, 81-2, 81-4, 81-5) acute toxicity categories as listed above.
- The acute inhalation study is still outstanding (81-3).
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 69361-UI is currently:

Acute Oral	IV
Acute Dermal	III
Acute Inhalation	outstanding
Primary Eye	III
Primary Dermal	III
Skin sensitization	skin sensitizer

LABELING:

ID #: 069361-UI

REPAR STREPTOMYCIN 50

SIGNAL WORD:

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any R,P, or HE filter, long sleeved shirt and long pants, shoes, socks, and chemical resistant gloves (such as or made out of any waterproof material, selection category A). Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 21, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MANDAVA ASSOCIATES, LLC
REPAR CORP
1050 CONN. AVE., N.W., SUITE 1000
WASHINGTON, DC 20036

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 19-NOV-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MANDAVA ASSOCIATES, LLC

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS

1050 CONNECTICUT AVENUE, N.W., SUITE 1000, WASHINGTON, DC 20036

Telephone: (202)-223-1424/1747 ⇒ Fax: (202)-223-0141 ⇒ E-MAIL: Mandava@compuserve.com

HAND DELIVERED

49515100

November 19, 2014

Ms. Hope Johnson
Product Manager (PM 21)
Fungicide Branch
Registration Division (7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

SUBJECT: ME-TOO Application for Registration
Product Name: **REPAR STREPTOMYCIN 50**
Active Ingredient: Streptomycin Sulfate
Company Name: Repar Corporation
Company Number: 69361

Dear Ms. Johnson

On behalf of Repar Corporation, we are submitting a **ME-TOO** application for the registration of **Repar Streptomycin 50** which is an end-use product containing streptomycin sulfate as an active ingredient (AI). The source for AI is Repar Strepto-Sulfate Technical (EPA Reg. No.: 69361-8).

In support of the application for the subject product registration, we are providing the following administrative materials and product chemistry data on **Repar Streptomycin 50**:

- 1) Application for Pesticide Registration –EPA Form 8570-1
- 2) Copy of Registration Fee Payment (Agency Tracking ID 74709951665)
- 3) Confidential Statement of Formula – EPA Form 8570-4
- 4) Formulator's Exemption for Repar Streptomycin 50 – EPA Form 8570-27
- 5) Certification with Respect to Citation of Data - EPA Form 8570-34
- 6) Data Matrix – EPA Form 8570-35
- 7) Five Copies of Draft Labeling for the Subject Product

REPAR STREPTOMYCIN 50

Page 2

Ms. Hope Johnson
November 19, 2014

- 8) Volume 1: REPAR STREPTOMYCIN 50: Product properties Data in Support of FIFRA Registration; Data Requirement: 40 CFR 158.300-355; OPPTS Series 830 (Project No.: REPAR-STREP50-PC11); Repar Corporation

The product chemistry data for the subject product was developed by Repar Corporation (EPA Company Number: 69361)

In addition to the above studies we are also relying on other items of data on the subject product in the Agency's files.

We are requesting an "**Expedited Review**" in accordance with FIFRA Section 3(c)(3)(b)(i), because our product (**Repar Streptomycin 50**) is similar or identical in composition and labeling to **AS-50 Agricultural Streptomycin** (EPA Reg. No. 55146-98).

Since we have fulfilled all of the registration requirements, we request you grant the registration for the subject products so that the applicant can market it for the 2015 growing season.

Sincerely,

N. Bhushan Mandava

N. Bhushan Mandava
Agent for Repar Corporation

Enclosure

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Repar Corporation
P.O. Box 4321
Silver Spring, MD 20914

REGULATORY ACTION SUPPORTED BY THIS PACKAGE:

FIFRA Reregistration Application for:

Product Name:	Repar Streptomycin 50
EPA Reg. No.:	To Be Assigned
Active Ingredient:	Streptomycin Sulfate
Chemical Code:	006310

TRANSMITTAL DATE:

November 19, 2014

LIST OF SUBMITTED STUDIES:

- 49515101 1) Volume 1: REPAR STREPTOMYCIN 50: Product properties Data in Support of FIFRA Registration; Data Requirement: 40 CFR 158.300-355; OPPTS Series 830 (Project No.: REPAR-STREP50-PC11); Repar Corporation

COMPANY OFFICIAL:

N. Bhushan Mandava

N. Bhushan Mandava
Registration Agent for Repar Corporation

COMPANY CONTACT:

N. Bhushan Mandava

Mandava Associates, LLC
1050 Connecticut Avenue, N.W., Suite 1000
Washington, D.C. 20036
(202) 223-1424/1747

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 11-19-14

Experts In-Processing Signature: B.B.

Date 11-21-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>69361-UI</u>		EPA Receipt Date: <u>11-19-14</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (<u>Electronic labels on CD</u> are encouraged and guidance is available)			X		
7	Is the data package consistent with <u>PR Notice 86-5</u>			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

* inerts approved for non-food use
 * submitted studies Passed PRN 11-3 Review
 * Jacket Passed

MRID: 495151

R 300 and 301

100% identical (repack): YES or NO (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	X	
830.1600	Description of materials used to produce the product	X	
830.1650	Description of formulation process	X	
830.1670	Discussion on the formation of impurities	X	
830.1700	Preliminary analysis	X	
830.1750	Certified limits (158.345)	X	
830.1800	Enforcement analytical method	X	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	X	
830.6303	Physical State	X	
830.6304	Odor	X	
830.6314	Oxidation/Reduction (Chemical incompatibility)	X	
830.6315	Flammability	X	
830.6316	Explodability	X	
830.6317	Storage stability	X	
830.6319	Miscibility	X	
830.6320	Corrosion Characteristics	X	
830.6321	Dielectric Breakdown voltage	X	
830.7000	pH	X	
830.7100	Viscosity	X	
830.7300	Density	X	

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	X	
870.1200	Acute Dermal (LD50)	X	
870.1300	Acute Inhalation (LC50)	X	
870.2400	Acute Eye Irritation	X	
870.2500	Acute Dermal Irritation	X	
870.2600	Dermal Sensitization	X	

Efficacy - which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			not required
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets			
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

November 20, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

**PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)**

OPP Decision Number: D-497484
EPA File Symbol or Registration Number: 69361-UI
Product Name: STREPTOMYCIN 50
EPA Receipt Date: 19-Nov-2014
EPA Company Number: 69361
Company Name: REPAR CORP

N. BHUSHAN MADAVA
MANDAVA ASSOCIATES, LLC
REPAR CORP
1050 CONN. AVE., N.W., SUITE 1000
WASHINGTON, DC 20036

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;
REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

The fee for action code R300 is \$1,506, of which you have paid \$452. Please remit additional payment in the amount of \$1,054 within 14 days to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (314) 425-1818

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{960690.~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 21

Receipt No.

S-

960690

EPA File Symbol/Reg. No.

69361-UI

Pin-Punch Date:

11/19/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R301

Granted: R300

Amount Due: \$ 1506

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Banza D.

Date: 11-20-14

Remarks:

*Unclear whether AT data is selectively cited
or uti-all.*

**Receipt****Your payment is complete**

Pay.gov Tracking ID: 25IGUG64

Agency Tracking ID: 74709951665

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Debit or credit card

Payment Amount: \$452.00

Transaction Date: 11/19/2014 12:16:18 PM EST

Payment Date: 11/19/2014

Registration Number:

Company Name: REPAR CORPORATION

Company Number: 69361

Action Code: R301

Account Information

Card Holder Name: N. Bhushan Mandava

Billing Address: 15404 Tindlay Street

Billing Address 2:

City: Silver Spring

Country: United States

State/Province: MD

ZIP/Postal Code: 20905

Card Type: American Express

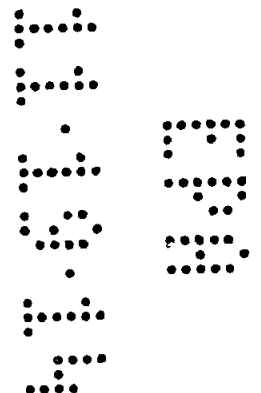
Card Number: *****5006

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

mandava@compuserve.com

srini@mandava.com





United States
Environmental Protection Agency
Washington, DC 20460

☒
☐
☐

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 69361-	2. EPA Product Manager Hope Johnson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Repar Streptomycin 50	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) Repar Corporation P.O. Box 4321 Silver Spring, MD. 20914 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 55146-98 Product Name AS-50 Agricultural Streptomycin	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

- 1) Application for FIFRA Section 3 Registration. Submission of Product Chemistry Studies in support of registration of Repar Streptomycin 50.
- 2) The action covered is New Product, Me-Too Product, Fast Track since the application is for formulation product registration that is substantially similar and/or identical to a currently registered product as cited in this application. The company Number is 69361. The file symbol is not assigned.
- 3) The applicant requested fee waiver.
- 4) Please direct all correspondence to: Mandava Associates, LLC; 1050 Connecticut Avenue, NW / Suite 1000; Washington, D.C. 20036
- 5) The contact Person fax number is (202) 223 - 0141 and e-mail address is: mandava@compuserve.com.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 10, 15, 25 lbs		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name N. Bhushan Mandava	Title Agent for Repar Corporation	Telephone No. (Include Area Code) (202) 223-1424	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received [Stamp]
2. Signature N. Bhushan Mandava	3. Title Agent for Repar Corporation		
4. Typed Name N. Bhushan Mandava	5. Date November 19, 2014		



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20910	EPA File Symbol/Registration Number 69361-
	Product Name REPAR STREPTOMYCIN 50
	Date of Confidential Statement of Formula (EPA Form 8570-4) 11/19/2014

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Streptomycin Sulfate : D-Streptamine,
O-2-deoxy-2-(methylamino)- α -L-glucopyranosyl-(1-62)-O-5-deoxy-3-C-formyl- α -L-lyxofuranosyl-(1-64)-N1,N3-bis(aminoimino-methyl)-, sulfate (2:3) (salt)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement.

That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Streptomycin Sulfate : D-Streptamine, O-2-deoxy-2-(methylamino)- α -L-glucopyranosyl-(1-62)-O-5-deoxy-3-C-formyl- α -L-lyxofuranosyl-(1-64)-N1,N3-bis(aminoimino-methyl)-, sulfate (2:3) (salt)	[REDACTED]	[REDACTED]
	[REDACTED]	[REDACTED]
Signature N. Bhushan Naudas	Name and Title Agent for Repar Corporation	Date 11/19/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Repar Corporation P.O. Box 4321 Silver Spring, MD 20914; (202) 223-1424	EPA Registration Number/File Symbol 69361- W
Active Ingredient(s) and/or representative test compound(s) Streptomycin Sulfate (CAS # 3810-74-0)	Date November 19, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Fungicide, Terrestrial, Food Crops	Product Name Repar Streptomycin 50

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature *N. Bhushan Mandava*

Date
Nov. 19, 2014

Typed or Printed Name and Title
N. Bhushan Mandava, Agent for Repar Corporation



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0080

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 3/23/2015		EPA Reg No./File Symbol 69361-UI		Page 1 of 6	
Applicant's/Registrant's Name & Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20914		Product Repar Streptomycin 50			
Ingredient Streptomycin Sulfate (CAS # 3810-74-0)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Repar Corporation	OWN	
			P.O. Box 4321 Silver Spring, MD 20914		
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
Signature <i>N. Bhushan Mandava</i>			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar Corporation		Date 03/23/2015

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DATA MATRIX

Date 3/23/2015		EPA Reg No./File Symbol 89381-UI		Page 2 of 6	
Applicant's/Registrant's Name & Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20914		Product Repar Streptomycin 50			
Ingredient Streptomycin Sulfate (CAS # 3810-74-0)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Repar Corporation		
			Repar Corporation		
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
Signature N. Bhushan Mandava			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar Corporation		Date 03/23/2015

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DATA MATRIX

Date 3/23/2015		EPA Reg No./File Symbol 69361-UI		Page 3 of 6	
Applicant's/Registrant's Name & Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20914		Product Repar Streptomycin 50			
Ingredient Streptomycin Sulfate (CAS # 3810-74-0)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	OWN	
			Repar Corporation	PAY	
			Repar Corporation	PAY	
			Repar Corporation	PAY	
			Repar Corporation	PAY	
			Repar Corporation	PAY	
Repar Corporation	PAY				
Signature N. Bhushan Mandava			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar Corporation		Date 03/23/2015

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DATA MATRIX

Date 3/23/2015		EPA Reg No./File Symbol 68361-U1		Page 4 of 6	
Applicant's/Registrant's Name & Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20914		Product Repar Streptomycin 50			
Ingredient Streptomycin Sulfate (CAS # 3810-74-0)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Crop Protection, LLC.	Pay	
			P.O. Box 18300, 410 Swing Road		
			Greensboro, NC 27419 (Company # 100)		
			HACO, INC.	Pay	
			P.O. Box 7190		
			Madison, WI 53707 (Company # 2393)		
			Wilbur-Ellis Company	Pay	
			2903 S. Cedar Avenue		
			Fresno, CA 93725 (Company # 2935)		
			Amvac Chemical Corporation	Pay	
			4695 Macarthur Court, Suite 1200		
			Newport Beach, CA 92660 (company # 5481)		
			Gustafson, LLC.	Pay	
			P.O. Box 660085		
			Dallas, TX 75266 (Company # 7501)		
Signature N. Bhushan Mandava		Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar Corporation		Date 03/23/2015	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Form Approved OMB No. 2070-0080

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DATA MATRIX

Date 3/23/2015		EPA Reg No./File Symbol 69361-UI		Page 5 of 6	
Applicant's/Registrant's Name & Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20914		Product Repar Streptomycin 50			
Ingredient Streptomycin Sulfate (CAS # 3810-74-0)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Nufarm Americas, Inc.	Pay	
			4020 Aerial Center Pkwy., Ste 101		
			Morrisville, NC 27560 (Company # 55146)		
			Makhteshim Agan of North America, Inc.	Pay	
			3120 Highwoods Blvd., Suite 100		
			Raleigh, NC 27604 (Company # 66222)		
			Spray Drift Task Force	Pay	
			1900 K Street, NW		
			Washington, DC 20006 (Company # 66607)		
			Geo Logic Corporation	Pay	
			4800 Hampden Lane, 7th Floor		
			Bethesda, MD 20814 (Company # 71185)		
			Outdoor Residential Exposure Task Force	Pay	
			1350 I Street, N.W.		
Washington, DC 20005 (Company # 71754)					
Signature N. Bhushan Mandava			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar Corporation		Date 03/23/2015

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DATA MATRIX

Date 3/23/2015		EPA Reg No./File Symbol 69361-UI		Page 6 of 6	
Applicant's/Registrant's Name & Address Repar Corporation P.O. Box 4321 Silver Spring, MD 20914		Product Repar Streptomycin 50			
Ingredient Streptomycin Sulfate (CAS # 3810-74-0)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Agricultural Reentry Task Force	Pay	
			1350 I Street, N.W.		
			Washington, DC 20005 (company # 71755)		
			FIFRA Endangered Species Task Force, LLC	Pay	
			1350 I Street, N.W.		
			Washington, DC 20005 (Company # 73989)		
			Agricultural Handler Exposure Task Force	Pay	
			P.O. Box 509, 1720 Prospect Drive		
			Macon, MO 63552 (Company # 75234)		
			Agrosource, INC.	Pay	
			4800 Hampden Lane, 7th Floor		
			Bethesda, MD 20814 (Company # 80990)		
			Generic Endangered Species Task Force	Pay	
			4110 136th Street, Northwest		
Gig Harbor, WA 98332 (Company # 84853)					
Signature <i>N. Bhushan Mandava</i>			Name and Title N. Bhushan Mandava, Ph.D., Agent for Repar Corporation		Date 03/23/2015

